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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Carlos Cordon-Cardo et al.  
Serial No.: 09/329,917 Examiner: Not Yet Known  
Filed : June 10, 1999 Group Art Unit: 1614  
For : MARKERS FOR PROSTATE CANCER

1185 Avenue of the Americas  
New York, New York 10036  
May 23, 2000

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

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INFORMATION DISCLOSURE STATEMENT

Applicants submit herewith an Information Disclosure Statement under 37 C.F.R. §1.56.

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants direct the Examiner's attention to the following disclosures:

1. U.S. Patent No. 5,688,665 (Massague et al.) issued November 18, 1997. (Exhibit 1)
2. Agus, D.B., et al., (1999) "Response of Prostate Cancer to Anti-Her-2/neu Antibody in Androgen-dependent and -independent Human Xenograft Models", Cancer Res. 59:4761-4764. (Exhibit 2)
3. Agus, D.B., et al., (1999) "Prostate Cancer Cell Cycle

Applicants: Carlos Cordon-Cardo  
U.S. Serial No.: 09/329,917  
Filed: June 10, 1999  
Page 2

Regulators: Response to Androgen Withdrawal and Development of Androgen Independence", J. Natl. Cancer Inst. **91**:1869-1876.  
(Exhibit 3)

4. Aprikian, A.G., et al., (1994) "Immunohistochemical Determination of P53 Protein Nuclear Accumulation in Prostatic Adenocarcinoma", Jrnl. of Urol. **151**:1276-1280. (Exhibit 4)
5. Campbell, M.J., et al., (1997) "Inhibition of proliferation of prostate cancer cells by a 19-nor-hexafluoride vitamin D<sub>3</sub> analogue involves the induction of p21<sup>waf1</sup>, p27<sup>kip1</sup> and E-cadherin", Journal of Molecular Endocrinolgy **19**:15-27.  
(Exhibit 5)
6. Cohen, D.W., et al., (1994) "Expression of Transforming Growth Factor- $\alpha$  and the Epidermal Growth Factor Receptor in Human Prostate Tissues", J. Urol. **152**:2120-2124. (Exhibit 6)
7. Cordon-Cardo C., et al., (1998) "Distinct Altered Patterns of p27<sup>KIP1</sup> Gene Expression in Benign Prostatic Hyperplasia and Prostatic Carcinoma", J. Natl. Cancer Inst. **90**:1284-1291,  
(Exhibit 7)
8. Cote, R.J., et al., (1998) "Association of p27<sup>KIP1</sup> Levels With Recurrence and Survival in Patients With Stage C Prostate Carcinoma", J. Natl. Cancer Inst. **90(12)**: 916-920. (Exhibit 8)

Applicants: Carlos Cordon-Cardo  
U.S. Serial No.: 09/329,917  
Filed: June 10, 1999  
Page 3

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9. Di Cristofano, A., et al., (1998) "Pten is essential for embryonic development and tumour suppression", Nature Genetics 19:348-355. (Exhibit 9)
10. Gou, Y., et al., (1997) "Loss of the Cyclin-dependent Kinase Inhibitor p27<sup>Kip1</sup> Protein in Human Prostate Cancer Correlates with Tumor Grade<sup>1</sup>", Clinical Cancer Research 3:2269-2274. (Exhibit 10)
11. Hengst, L., et al., (1996) "Translational Control of p27<sup>Kip1</sup> Accumulation During the Cell Cycle", Science 271:1861-1864. (Exhibit 11)
12. Knudsen, K.E., et al., (1998) "Multiple G<sub>1</sub> Regulatory Elements Control the Androgen-dependent Proliferation of Prostatic Carcinoma Cells", Journal of Biological Chemistry 273(32): 20213-20222. (Exhibit 12)
13. Kokontis, J.M., et al., (1998) "Progression of LNCaP Prostate Tumor Cells During Androgen Deprivation: Hormone-Independent Growth, Repression of Proliferation by Androgen, and Role for p27<sup>Kip1</sup> in Androgen-Induced Cell Cycle Arrest", Molecular Endocrinology, 12:941-953. (Exhibit 13)
14. Lacombe, L., et al., (1996) "Microsatellite Instability and Deletion Analysis of Chromosome 10 in Human Prostate Cancer", Int. J. Cancer 69:110-113. (Exhibit 14)

Applicants: Carlos Cordon-Cardo  
U.S. Serial No.: 09/329,917  
Filed: June 10, 1999  
Page 4

15. Lee, C.T., et al., (1999) "Overexpression of the Cyclin-dependent Kinase Inhibitor p16 is Associated with Tumor Recurrence in Human Prostate Cancer<sup>1</sup>", Clin. Cancer Res. 5:977-983. (Exhibit 15)
16. Osman, I., et al., (1997) "Chromosome 16 in Primary Prostate Cancer: A Microsatellite Analysis", Int. J. Cancer 71:580-584. (Exhibit 16)
17. Osman, I., et al. (1999) "Inactivation of the p53 Pathway in Prostate Cancer: Impact on Tumor Progression<sup>1</sup>", Clinical Cancer Research 5:2082-2088. (Exhibit 17)
18. Ponce-Castaneda, M.V., et al., (1995) "p27<sup>Kip1</sup>: Chromosomal Mapping to 12p12-12p13.1 and Absence of Mutations in Human Tumors". Cancer Research 55:1211-1214. (Exhibit 18)
19. Polyak, K., et al., (1994) "Cloning of p27<sup>Kip1</sup>, a Cyclin-Dependent Kinase Inhibitor and a Potential Mediator of Extracellular Antimitogenic Signals", Cell 78:59-66. (Exhibit 19)
20. Polyak, K., et al., (1994) "p27<sup>Kip1</sup>, a Cyclin-Cdk Inhibitor, links transforming growth factor- $\beta$  and contact inhibition to cell cycle arrest", Genes & Development 8:9-22. (Exhibit 20)
21. Scher, H.I., et al., (1995) "Changing Pattern of Expression of

Applicants: Carlos Cordon-Cardo  
U.S. Serial No.: 09/329,917  
Filed: June 10, 1999  
Page 5

the Epidermal Growth Factor Receptor and Transforming Growth Factor  $\alpha$  in the Progression of Prostatic Neoplasms<sup>1</sup>", Clinical Cancer Research 1:545-550. (Exhibit 21)

22. Silver, D.A., et al., (1997) "Prostate-specific Membrane Antigen Expression in Normal and Malignant Human Tissues<sup>1</sup>", Clinical Cancer Research 3:81-85. (Exhibit 22)
23. Simak, R., et al., (2000) "Expression of c-kit and kit-ligand in benign and malignant prostatic tissues", Histol Histopathol 15:365-374. (Exhibit 23)

The subject application is a continuation-in-part of PCT International Application No. PCT/US98/25483, filed December 1, 1998, claiming benefit of U.S. Provisional Application No. 60/067,190, filed December 1, 1997. Each of the above-listed references is listed on the accompanying PTO Form 1449 as **Exhibit A**.

Above-listed references 1, 5, 8, 10-13, and 18-20 were cited in the International Search Report in connection with PCT International Application No. PCT/US98/25483, filed on March 2, 1999. A copy of the International Search Report is attached hereto as **Exhibit B**. A copy of references 1-23 are attached hereto as **Exhibits 1-23**.

Applicants: Carlos Cordon-Carido  
U.S. Serial No.: 09/329,917  
Filed: June 10, 1999  
Page 6



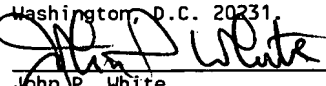
Applicants request that the Examiner review the references and make them of record in the subject application.

If a telephone conference would be of assistance in advancing the prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone at the number provide below.

No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully yours,

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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage a first class mail in an envelope addressed to:	
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